

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SAN ROCCO THERAPEUTICS, LLC,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 21-1478-RGA
v.	)	
	)	
BLUEBIRD BIO, INC. and THIRD ROCK	)	
VENTURES, LLC,	)	
	)	
Defendants.	)	

**PLAINTIFF'S ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS'  
MOTION TO STAY CASE PENDING *INTER PARTES* REVIEW PROCEEDINGS**

*Of Counsel:*

YOUNG CONAWAY STARGATT  
& TAYLOR, LLP

Wanda D. French-Brown  
Howard S. Suh  
James H. McConnell  
FOX ROTHSCHILD LLP  
101 Park Avenue, 17th Floor  
New York, NY 10178  
(646) 601-7617  
wfrench-brown@foxrothschild.com  
hsuh@foxrothschild.com  
jmccconnell@foxrothschild.com

Anne Shea Gaza (No. 4093)  
Samantha G. Wilson (No. 5816)  
Rodney Square  
1000 North King Street  
Wilmington, DE 19801  
(302) 571-6600  
agaza@ycst.com  
swilson@ycst.com

*Attorneys for Plaintiff  
San Rocco Therapeutics, LLC*

Joe G. Chen, Ph.D.  
FOX ROTHSCHILD LLP  
997 Lenox Drive  
Lawrenceville, NJ 08648  
(609) 844-3024  
joechen@foxrothschild.com

Dated: June 7, 2023

Lenore Horton  
HORTON LEGAL STRATEGIES PLLC  
11 Broadway, Suite 615  
New York, NY 10004  
(212) 888-9140  
lenore@hortonlegalstrategies.com

**TABLE OF CONTENTS**

I.	NATURE AND STAGE OF THE PROCEEDINGS & STATEMENT OF FACTS .....	1
II.	SUMMARY OF THE ARGUMENT .....	2
III.	ARGUMENT: A SECOND STAY IN THIS CASE SHOULD NOT BE GRANTED .....	3
A.	A Stay Will Not Simplify the Issues.....	4
B.	A Second Stay Would Unduly Prejudice SRT And Permit Defendants to Gain Improper Tactical Advantages .....	9
1.	The Timing of the IPR Petitions Illustrate Defendants’ Dilatory Intent .....	10
2.	The Timing of the Second Stay Request Disfavors Granting Defendants’ Motion and Will Prejudice SRT .....	12
3.	The Relationship Between the Parties Disfavors a Stay .....	13
4.	The IPRs Should Have Never Been Filed.....	16
C.	The Stage of the Litigation Does Not Warrant a Stay .....	19
IV.	CONCLUSION.....	19

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Cases</b>	
<i>Avanos Med. Sales, LLC v. Medtronic Sofamor Danek USA, Inc.</i> , C.A. No. 2:19-cv-02754, 2020 WL 7865959 (W.D. Tenn. Nov. 24, 2020).....	14
<i>Becon Med., Ltd. v. Bartlett</i> , C.A. No. 18-4169, 2019 WL 6910130 (E.D. Pa. Dec. 18, 2019) .....	14, 15
<i>Belden Techs. Inc. v. Superior Essex Commc'ns LP</i> , C.A. No. 08-63-SLR, 2010 WL 3522327 (D. Del. Sept. 2, 2010) .....	10
<i>CAO Lighting, Inc. v. Gen. Elec. Co.</i> , C.A. Nos. 20-681, 20-690-GBW, 2022 WL 17752270 (D. Del. Dec. 19, 2022) .....	5
<i>CMG Worldwide Inc. v. Adidas Am., Inc.</i> , C.A. No. 1:17-cv-2356-RLM-DML, 2018 WL 7140117 (S.D. Ind. Sept. 26, 2018) .....	15
<i>Collabo Innovations, Inc. v. Sony Corp.</i> , C.A. No. 15-1094-RGA, D.I. 43 (D. Del. Jan. 5, 2017) .....	6
<i>F'Real Foods, LLC v. Hamilton Beach Brands, Inc.</i> , C.A. No. 16-41-GMS, 2017 WL 10619854 (D. Del. March 9, 2017).....	4, 13, 14
<i>ImageVision.Net, Inc. v. Internet Payment Exch., Inc.</i> , C.A. No. 12-054-GMS-MPT, 2013 WL 1743854 (D. Del. Apr. 22, 2013) .....	3, 4, 13
<i>Intell. Ventures I LLC v. Hewlett Packard Enter. Co.</i> , C.A. No. 6:21-cv-00596, D.I. 104 (W.D. Tex. Dec. 22, 2022) .....	8
<i>Intell. Ventures I LLC v. Toshiba Corp.</i> , C.A. No. 13-453-SLR-SRF, 2015 WL 3773779 (D. Del. May 15, 2015).....	5, 15
<i>Laborers' Intern. Union of N. Am., AFL-CIO v. Foster Wheeler Energy Corp.</i> , 26 F.3d 375 (3d Cir. 1994).....	7
<i>Neste Oil OYJ v. Dynamic Fuels, LLC</i> , C.A. No. 12-1744-GMS, 2013 WL 3353984 (D. Del. July 2, 2013).....	9, 10, 12, 13
<i>Oracle Corp. v. Parallel Networks, LLP</i> , C.A. No. 06-414-SLR, 2010 WL 3613851 (D. Del. Sept. 8, 2010) .....	5
<i>Peloton Interactive, Inc. v. Flywheel Sports, Inc.</i> , C.A. No. 2:18-cv-00390-RWS-RSP, 2019 WL 3826051 (E.D.Tex. Aug. 14, 2019) .....	8

<i>President and Fellows of Harvard College v. Micron Tech., Inc.</i> , C.A. No. 17-1729-LPS-SRF, 2018 WL 10337332 (D. Del. Jan. 8, 2018) .....	6, 9
<i>RainDance Techs, Inc. v. 10X Genomics, Inc.</i> , C.A. No. 15-152-RGA (D. Del. Apr. 5, 2016) .....	15
<i>Robinson v. Walgreen Co.</i> , C.A. No. 20 CV 50288, 2021 WL 2453069 (N.D. Ill. Jun. 16, 2021) .....	15
<i>SAS Institute, Inc. v. Iancu</i> , 138 S. Ct. 1348 (2018) .....	8
<i>SenoRx, Inc. v. Hologic, Inc.</i> , C.A. No. 12-173-LPS-CJB, 2013 WL 144255 (D. Del. Jan. 11, 2013) .....	3, 4, 10, 19
<i>SoftView LLC v. Apple Inc.</i> , C.A. No. 10-389-LPS, 2012 WL 3061027 (D. Del. July 26, 2012) .....	5
<i>Teleconference Sys. v. Proctor &amp; Gamble Pharms., Inc.</i> , 676 F. Supp. 2d 321 (D. Del. 2009) .....	7
<i>Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.</i> , 193 F. Supp. 3d 345 (D. Del. 2016) .....	4, 9, 10
<i>Toshiba Tec Corp. v. Katun Corp.</i> , C.A. No. 15-01979-SJO, 2016 WL 9137646 (C.D. Cal. Sept. 21, 2016) .....	9
<i>VirtualAgility Inc. v. Salesforce.com, Inc.</i> , 759 F.3d 1307 (Fed. Cir. 2014) .....	15

## **Statutes**

18 U.S.C. § 1964 <i>et seq.</i> .....	17
35 U.S.C. § 101 .....	4, 5, 7, 8
35 U.S.C. § 102 .....	4, 6, 7
35 U.S.C. § 103 .....	4, 6, 7
35 U.S.C. § 112 .....	4, 5, 7, 8
35 U.S.C. § 116 .....	4, 7, 8
35 U.S.C. § 311(b) .....	4
35 U.S.C. § 314(b) .....	12
35 U.S.C. § 316(a)(11) .....	12

Mass. Gen. Law ch. 93A, § 11.....	17
-----------------------------------	----

**Other Authorities**

37 CFR § 42.107(b) .....	12
--------------------------	----

D. Del. LR 7.1.3(c)(2).....	7
-----------------------------	---

Fed. R. Civ. P. 12(b)(1).....	1
-------------------------------	---

Fed. R. Civ. P. 12(b)(6).....	1
-------------------------------	---

Plaintiff San Rocco Therapeutics, LLC (“SRT”) respectfully submits this opposition brief to Defendants bluebird bio, Inc.’s (“bluebird”) and Third Rock Ventures, LLC (“TRV”) (collectively, “Defendants”) motion to stay proceedings pending resolution of two petitions for *inter partes* review (“IPR”) (hereafter, “Motion”).

## **I. NATURE AND STAGE OF THE PROCEEDINGS & STATEMENT OF FACTS**

On October 21, 2021, SRT sued bluebird for infringement of U.S. Patents Nos. 7,541,179 (“the ’179 Patent”) and 8,058,061 (“the ’061 Patent”) (collectively, the “Patents-in-Suit.”). (D.I. 1.) On November 17, 2021, SRT filed an amended complaint, adding TRV as a defendant. (D.I. 9.) Following Defendants’ first motion to dismiss pursuant to Rules 12(b)(1) and (6) of the Federal Rules of Civil Procedure or, alternatively, to compel arbitration and stay the proceedings (D.I. 15), the Court granted SRT leave to file a second amended complaint (“SAC”). (D.I. 38.) Defendants’ second motion to dismiss or, alternatively, to compel arbitration and stay proceedings was filed on April 6, 2022. (D.I. 44.) On July 26, 2022, the Court granted Defendants’ motion to compel arbitration and stay proceedings, and denied the motion to dismiss without prejudice, pending the resolution of the arbitration. (D.I. 76.) During arbitration, on October 18, 2022, Defendants filed two IPR petitions against some (but not all) of the claims of the Patents-in-Suit.

On February 7, 2023, arbitrator David W. Ichel (“Arbitrator”) issued an arbitration award in SRT’s favor with respect to all issues presented in arbitration. (*See* D.I. 86, 87.) On March 1, 2023, the parties filed a stipulation proposing that the Court lift the stay and that Defendants answer the SAC on or before March 31, 2023. (D.I. 86.) The Court lifted the stay on March 2, 2023. (D.I. 88.) On March 31, 2023, Defendants filed an Answer to the SAC and asserted counterclaims against SRT. (D.I. 90.) On April 21, 2023, SRT filed an Answer to Defendants’ counterclaims. (D.I. 93.) On May 24, 2023, and one day before the proposed scheduling order was due, Defendants filed the instant Motion for a second stay of this case, this time pending resolution of

two IPRs that Defendants waited twelve months to file in October 2022 after being served with SRT's complaint in October 2021. (D.I. 97.) On May 25, 2023, the Court issued the Scheduling Order and set a trial date for April 21, 2025. (D.I. 101.)

## II. SUMMARY OF THE ARGUMENT

For the reasons set forth herein, Defendants' second stay Motion should be denied.

**First**, a second stay will not simplify the issues in the district court litigation because the scope of the issues to be resolved during the litigation far exceeds the scope of the issues that can be decided by the Patent Trial and Appeal Board ("PTAB") during the IPR proceeding. Where, as here, the Court would have to resolve issues of infringement, inequitable conduct, prosecution history estoppel, infringement, and damages, the Motion should be denied. In its decision to institute, the PTAB made it clear that Defendants had not shown a reasonable likelihood of prevailing on, at least, two challenged claims. Moreover, even if Defendants' challenges to certain claims of the Patents-in-Suit are successful, the IPRs will not eliminate the need for trial given that not all asserted claims of the Patents-in-Suit are challenged during the IPR proceeding. (See discussion *infra* Section III-A.)

**Second**, a second stay in this case would unduly prejudice SRT (a direct competitor of bluebird) and permit Defendants to gain multiple improper tactical advantages. As an initial matter, the IPRs themselves are improper as the parties previously entered into agreements precluding Defendants from filing IPRs in the first place. Notwithstanding those agreements, Defendants filed IPRs, but waited twelve months after being served with SRT's initial complaint to do so and did so in the middle of arbitration and during the first stay of this case. The factual record in the arbitration illustrates that Defendants' IPR petitions were filed with dilatory intent and to gain a tactical advantage over SRT. (See discussion *infra* Section III-B-1.) SRT and

bluebird are direct competitors and there is strong evidence of willful infringement. Thus, SRT would be prejudiced by a stay. (*See* discussion *infra* Section III-B-3.)

**Third**, the stage of the litigation does not support a second stay. This case is not in the early stages. The parties have been litigating key preliminary and case dispositive issues for nearly twenty months. The first stay was caused by Defendants’ demand for arbitration based on two purported defenses: (i) SRT did not have an exclusive license, with all substantial rights, to the Patents-in-Suit, and thus had no standing to assert the Patents-in-Suit, and (ii) the mutual release provisions of a November 2, 2020 settlement agreement (“Settlement Agreement”) release SRT’s claims for patent infringement by Defendants. SRT won on all issues presented in arbitration. Now Defendants seek to use yet another collateral action—one which it admits will not resolve all issues in this case—to disadvantage SRT and delay resolution yet again. Indeed, the IPRs should have never been filed because Defendants released their rights to challenge the validity of the Patents-in-Suit in November 2020. (*See* discussion *infra* Sections III-B-3, III-C.)

As discussed herein, Defendants have not (and cannot) meet their burden of showing that a second stay, this time pending the outcome of the IPR proceedings, is warranted.

### **III. ARGUMENT: A SECOND STAY IN THIS CASE SHOULD NOT BE GRANTED**

It is well settled that the Court has broad discretion to deny a motion to stay, especially under the circumstances of this case where the moving party is seeking a second stay of proceedings that had been previously stayed. *ImageVision.Net, Inc. v. Internet Payment Exch., Inc.*, C.A. No. 12-054-GMS-MPT, 2013 WL 1743854, at \*3 (D. Del. Apr. 22, 2013). Courts typically consider three factors to determine whether a stay is appropriate: (1) whether granting the stay will simplify the issues for trial; (2) the status of the litigation, particularly whether a trial date has been set; and (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay or allow the movant to gain a clear tactical advantage. *SenoRx, Inc. v. Hologic,*



*Inc.*, C.A. No. 12-173-LPS-CJB, 2013 WL 144255, at \*2 (D. Del. Jan. 11, 2013) (denying motion to stay pending PTAB proceeding); *F’Real Foods, LLC v. Hamilton Beach Brands, Inc.*, C.A. No. 16-41-GMS, 2017 WL 10619854 (D. Del. March 9, 2017) (denying motion to stay pending PTAB decision); *ImageVision.Net, Inc.*, 2013 WL 1743854, at \*1 (denying motion to stay pending PTAB decision). The moving party has the heavy burden of showing that these factors tilt in its favor. *Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.*, 193 F. Supp. 3d 345, 353 (D. Del. 2016) (where a balancing of the stay factors did not favor either side and the motion “could go either way . . . [w]ith the movant not having shown that the equities tilt in its favor,” the court denied the motion to stay). Here, the factors tilt in favor of denying a stay and Defendants have not met their burden of showing otherwise.

#### **A. A Stay Will Not Simplify the Issues**

The institution of an IPR is limited to challenges to the validity of claims raised under 35 U.S.C. §§ 102 or 103 based solely on publicly available printed publications and patents. 35 U.S.C. § 311(b). Here, the IPRs do not impact all of the legal issues presented in the district court litigation. “The more that the scope of the issues to be resolved during the litigation exceeds the scope of the issues that can be examined during the [PTAB] proceeding, the greater this cuts against a finding that the [PTAB] proceedings will lead to simplification of the issues.” *SenoRx*, 2013 WL 144255, at \*4.

The IPR proceedings are limited to invalidity challenges arising under §§ 102 and 103 of certain claims (but not all asserted claims) of the Patents-in-Suit. However, Defendants’ Answer includes affirmative defenses and declaratory counterclaims of invalidity under §§ 101 (unpatentable subject matter), 112 (lack of written description and enablement) and 116 (improper inventorship) that far exceeds the scope of the IPR proceedings. (D.I. 90, at 68-69; Counterclaims, ¶¶ 47-50.) In addition, Defendants are asserting equitable defenses and counterclaims related to

inequitable conduct (*id.*, ¶¶ 32-36) and prosecution history estoppel (*id.*, ¶¶ 18, 28.) The IPR proceeding will not address issues of noninfringement, disputes related to the inventors alleged failure to disclose material prior art, prosecution history estoppel, and damages. Where, as here, the issues before the PTAB are not the only defenses asserted by Defendants, courts have denied a motion to stay pending the PTAB proceeding. *See, e.g., Oracle Corp. v. Parallel Networks, LLP*, C.A. No. 06-414-SLR, 2010 WL 3613851, at \*2 (D. Del. Sept. 8, 2010) (finding that an allegation of inequitable conduct disfavors a stay); *SoftView LLC v. Apple Inc.*, C.A. No. 10-389-LPS, 2012 WL 3061027, at \*3 (D. Del. July 26, 2012) (denying motion to stay where Defendants disputed invalidity under 35 U.S.C. §§ 101 and 112 and raised equitable defenses relating to estoppel and waiver); *Intell. Ventures I LLC v. Toshiba Corp.*, C.A. No. 13-453-SLR-SRF, 2015 WL 3773779, at \*3 (D. Del. May 15, 2015) (denying stay post-institution where “discovery on those products will proceed regardless of whether the stay is granted or not.”); *CAO Lighting, Inc. v. Gen. Elec. Co.*, C.A. Nos. 20-681, 20-690-GBW, 2022 WL 17752270, at \*2 (D. Del. Dec. 19, 2022) (denying motion to stay where “Defendants still maintain a variety of other defenses to the claims of infringement including” section 112 defenses, inequitable conduct, equitable estoppel. “None of these other defenses are part of the [] IPR or will ever be considered by the PTAB.”). Because the scope of the issues to be resolved during litigation substantially exceeds the scope of the issues that can be resolved by the PTAB, this factor does not favor a stay.

Contrary to Defendants’ claims, if successful, the IPRs will not eliminate the need for trial because Defendants did not challenge all asserted claims of the Patents-in-Suit. The SAC alleges that the BB305 Vector infringes *at least* claims 1 and 23 of the ’179 Patent and, and *at least* claims 1-2, 5, 7-8, 11 and 15 of the ’061 Patent (D.I. 39, ¶¶ 186, 198 (emphasis added).) SRT can (and will) assert other claims of the Patents-in-Suit that are not challenged in the IPR proceeding. For

example, SRT intends to assert claim 3 of the '061 Patent that is not challenged in the IPR because the accused BB305 Vector has “a nucleic acid encoding a selectable marker,” as required by that claim. In addition, Defendants did not challenge claim 23 of the '179 Patent in the IPR, and, thus, any and all invalidity issues concerning claim 23 must be resolved in the district court litigation regardless of the outcome of the IPR proceeding. *See, e.g., President and Fellows of Harvard College v. Micron Tech., Inc.*, C.A. No. 17-1729-LPS-SRF, 2018 WL 10337332 (D. Del. Jan. 8, 2018) (denying motion to stay noting “the Court will have to resolve issues of infringement and validity with respect to at least this [non-instituted] claim (even recognizing that [non-instituted claim] is dependent on claims for which IPR has been instituted)”); *Collabo Innovations, Inc. v. Sony Corp.*, C.A. No. 15-1094-RGA, D.I. 43 (D. Del. Jan. 5, 2017) (Ex. A) (denying stay where issues would have to be litigated regardless of IPRs).

Contrary to Defendants’ claims, the accused BB305 Vector has two “GATA-1 binding sites at the junction between the HS3-spanning and HS4-spanning nucleotide fragments,” as required by claim 23 of the '179 Patent. (*See* D.I. 98, (“Def. Br.”) at 4-5.) In any event, Defendants’ non-infringement arguments are neither relevant nor persuasive here. For purposes of determining the stay, as the moving party, Defendants cannot rely on arguments or evidence that the accused BB305 Vector does not infringe claim 23 of the '179 Patent, since by law, IPRs do not resolve issues of infringement, but only those pertaining to anticipation and obviousness under §§ 102 and 103. Defendants argue that bluebird’s BB305 Vector lacks certain limitations of asserted claim 23, which relate to infringement issues, while simultaneously claiming that it would be more efficient for the PTAB to resolve §§ 102 and 103 invalidity issues for only a few claims. (*Id.*) Defendants cannot have it both ways. Indeed, Defendants’ proposed stay would certainly not streamline all of the invalidity, enforceability and infringement issues presented in

this case. A stay will result in an undesired duplication of work related to patentability of the Patents-in-Suit.

Defendants have not specifically shown how litigating patent invalidity under §§ 101, 112, 116, enforceability, and infringement issues in parallel with the IPR proceedings (*i.e.*, §§ 102 and 103 invalidity issues) would make the case more complex or could lead to inconsistent findings. (Def. Br. at 5-6.) In fact, Defendants have not provided one credible specific factual example demonstrating that litigating the district court case and IPR proceeding in parallel would be too complex or lead to inconsistent results. (*Id.*) Moreover, Defendants have not specifically identified facts illustrating how the IPR proceeding (*i.e.*, §§ 102 and 103 invalidity issues) would streamline the other patent issues (*e.g.*, §§ 101, 112, 116 invalidity issues, prosecution history estoppel, infringement, failure to disclose material prior art) to be litigated in this case. Rather, in their opening brief, Defendants provide conclusory legal arguments lacking in facts. (*Id.*) And it is too late for Defendants to try to present new factual examples or arguments in their reply brief. *See, e.g., Teleconference Sys. v. Proctor & Gamble Pharms., Inc.*, 676 F. Supp. 2d 321, 331 n.13 (D. Del. 2009) (“Issues raised for the first time in a reply brief should not be heard.”); *Laborers’ Intern. Union of N. Am., AFL-CIO v. Foster Wheeler Energy Corp.*, 26 F.3d 375, 398 (3d Cir. 1994) (“An issue is waived unless a party raises it in its opening brief, and for those purposes ‘a passing reference to an issue . . . will not suffice to bring that issue before this court.’”) (citation omitted); D. Del. LR 7.1.3(c)(2) (“The party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief.”). Defendants have failed to meet their burden here.

Defendants will likely not succeed in the IPR proceeding. Here, Defendants admit that ***“[t]he PTAB found that the IPR petitions had not shown a reasonable likelihood of prevailing***

*for two of the challenged claims.”* (Def. Br. at 5 n.3.) (emphasis added). As Defendants concede, the PTAB made clear that Defendants failed to meet their burden as to claim 10 of the ’179 Patent and claim 8 of the ’061 Patent (also identified in SRT’s original complaint). (D.I., 95, Ex. A, IPR2023-00070, Paper 8 at 6, 50; D.I., 95, Ex. B, IPR2023-00074, Paper 8 at 6, 51.) Therefore, based on the initial determination provided by the PTAB, at least claim 10 of the ’179 Patent and claim 8 of the ’061 Patent, with respect to invalidity under §§ 101, 112, and 116, will likely need to be resolved in the district court litigation. Defendants’ arguments for the remaining challenged claims in the IPR proceedings are similarly without merit. Several of the grounds in the IPRs rely on the “May Thesis” as a prior art reference, but the PTAB determined that the May Thesis was not prior art. (*Id.*, at 6, 28-29.) The remaining grounds are strongly disputed by SRT, which has yet to file its full Patent Owner Response.

Because the PTAB can no longer exclude valid claims from institution post-*SAS*,<sup>1</sup> courts have recognized that “an institution decision is less effective as a barometer for the issue of whether the PTAB will eventually determine that the challenged claims are unpatentable after *SAS*.” *See Peloton Interactive, Inc. v. Flywheel Sports, Inc.*, C.A. No. 2:18-cv-00390-RWS-RSP, 2019 WL 3826051, at \*2 (E.D.Tex. Aug. 14, 2019) (“When the PTAB decides to institute review after *SAS*, it must institute review for all challenged claims even if the PTAB concludes at the petition stage that the petitioner did not show a reasonable likelihood that it would prevail for some challenged claims.”); *Intell. Ventures I LLC v. Hewlett Packard Enter. Co.*, C.A. No. 6:21-cv-00596, D.I. 104 at 6-7 (W.D. Tex. Dec. 22, 2022) (denying motion to stay where defendant failed to show IPR institution was likely to result in invalidity of all challenged claims) (Ex. B). Even Defendants concede that there is no reasonable likelihood of prevailing on all challenged claims. (Def. Br. at

---

<sup>1</sup> *See SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018) (banning partial institutions).

5 n.3.) And even if Defendants were successful in invalidating every challenged claim—despite the PTAB’s express statements to the contrary—it would still not address every asserted claim in this litigation.

Where, as here, the Court would have to resolve issues of infringement and invalidity with respect to one or more remaining claims not challenged by the IPR, the motion to stay should be denied. *See, e.g., President and Fellows of Harvard College*, 2018 WL 10337332, at \*1 (denying motion to stay); *Toshiba Samsung Storage Tech.*, 193 F. Supp. 3d at 353 (denying motion to stay); *Toshiba Tec Corp. v. Katun Corp.*, C.A. No. 15-01979-SJO (JCx), 2016 WL 9137646, at \*4 (C.D. Cal. Sept. 21, 2016) (“courts regularly deny motions to stay where IPRs were instituted on only a portion of the claims asserted”). Accordingly, the first factor weighs against a stay.

**B. A Second Stay Would Unduly Prejudice SRT And Permit Defendants to Gain Improper Tactical Advantages**

Defendants’ Motion seeks a second stay in this case, which began nearly twenty months ago in October 2021. When requesting the first stay, Defendants argued that that stay was warranted because arbitration would resolve critical case dispositive issues that had to be resolved before Defendants filed an Answer. After filing their Answer, Defendants tactically seek to use another collateral proceeding—one which will admittedly not resolve all issues in this case—to repeat the process and delay resolution yet again.

Courts are mindful of the fact that staying any case pending IPR review by the PTAB naturally risks prolonging the final resolution of the pending case and, as such, results in some inherent prejudice to the non-moving party. *See, e.g., Neste Oil OYJ v. Dynamic Fuels, LLC*, C.A. No. 12-1744-GMS, 2013 WL 3353984, at \*2 (D. Del. July 2, 2013). Courts typically examine the following factors in determining whether a stay will likely result in undue prejudice to the plaintiff or whether a defendant would gain an unfair tactical advantage if a stay is granted: (1) the timing

of the request for the IPR; (2) the time of the request for the stay; (3) the status of the IPR proceeding; and (4) the relationship of the parties. *SenoRx*, 2013 WL 144255, at \*6-7; *Toshiba Samsung Storage Tech.*, 193 F. Supp. 3d at 350-52.

### **1. The Timing of the IPR Petitions Illustrate Defendants’ Dilatory Intent**

Courts are reluctant to grant a stay where, as here, the timing of IPR petitions suggests a dilatory intent on the movant’s part. *See, e.g., Neste Oil OYJ*, 2013 WL 3353984, at \*2; *Belden Techs. Inc. v. Superior Essex Commc’ns LP*, C.A. No. 08-63-SLR, 2010 WL 3522327, at \*2 (D. Del. Sept. 2, 2010) (“A request for reexamination made well after the onset of litigation followed by a subsequent request to stay may lead to an inference that the moving party is seeking an inappropriate tactical advantage.”). Defendants first moved to stay this case in favor of arbitration to resolve their claims that SRT was not an exclusive licensee with all substantial rights to the Patents-in-Suit and could not stand in the place of the patent owner, Sloan Kettering Institute of Cancer Research (“SKI”). That stay was granted and arbitration ensued. Defendants then waited until twelve months after service of the initial complaint, and in the midst of the arbitration, to file the IPR petitions. This record reflects that Defendants waited—until after the Court granted their first motion to stay pending arbitration—to leverage their IPR petitions at a time when their filing could gain a tactical advantage over SRT, including in the pending arbitration.

During arbitration, on October 18, 2022, Defendants served SKI and SRT with their petitions. On November 8, 2022, SRT filed the Patent Owner’s Mandatory Notices (“POMN”) with the PTAB—and SRT did so because, as the exclusive licensee, it has the responsibility to defend the validity of the Patents-in-Suit, at SRT’s expense. (*See* Ex. C at 2, (SRT’s December 15, 2022, Response to Defendants’ Arbitration Procedural Application).) Defendants then sought to exclude SRT from participating in the IPR proceedings unless SRT could immediately provide proof that it had standing to defend the validity of the Patents-in-Suit. (*See* D.I. 87 ¶ 62 (Arbitrator

Award stating: “Respondents’ counsel between November 21 and December 1, 2022 sent a series of emails demanding documentation as to SRT’s rights to the patents in the IPR proceeding.”)). For example, on November 21, 2022, Defendants’ IPR counsel demanded copies of certain communications between SRT and SKI and other materials establishing SRT’s standing to defend the validity of the Patents-in-Suit before the PTAB. (*See id.*) Not satisfied with SRT’s response, on November 28, Defendants’ IPR counsel indicated they would contact the PTAB because SRT did not voluntarily provide copies of its communications with SKI that were referenced in the POMN and included a draft correspondence to the PTAB in that email. (*See id.*) On November 29, SRT reiterated that PTAB Rules do not require SRT to provide Defendants with copies of their communications with SKI and offered to contact SKI to get their availability to join any call with the PTAB. (*See id.*)

Challenges from Defendants’ IPR counsel continued. In response, Defendants stated that “SRT has not established that it is the exclusive licensee with all substantial rights to the patents-at-issue,” and they “will hold off on sending the email to the [PTAB] until tomorrow, so that [SRT] may obtain SKI’s availability for a call with the [PTAB].” (*Id.*) On December 1, 2022, Defendants continued to demand that SRT provide them with proof that SRT is entitled to file a preliminary response in the IPR proceedings, *e.g.*, by showing that it is the exclusive licensee with all substantial rights to the patents-at-issue. (*Id.*) During a December 2, 2022 meet and confer, SRT informed Defendants that its arbitration opening brief would include evidence that SRT is entitled to file a Patent Owner’s Preliminary Response (“POPR”) with the PTAB and participate in the IPR proceedings. That same day, SRT’s opening brief was filed with the evidence promised, such as a December 2, 2022, exclusive patent license agreement executed between SRT and SKI and Memorial Sloan Kettering Cancer Center (“MSKCC” and collectively with SKI, “MSK”).



Accordingly, the record reflects Defendants' dilatory intent and attempt to gain a tactical advantage over SRT, including with respect to the parties' dispute over standing, and at a time when the filing of the IPRs could gain maximum tactical advantage over SRT, including in the pending arbitration.

Accordingly, Defendants waited—until after the Court granted their first motion to stay pending arbitration—to file the IPR petitions during arbitration simply to gain a tactical advantage.

## **2. The Timing of the Second Stay Request Disfavors Granting Defendants' Motion and Will Prejudice SRT**

“A delay in filing a motion to stay may indicate that the movant,” like the Defendants here, “sought to gain an improper tactical advantage.” *Neste Oil OYJ*, 2013 WL 3353984, at \*2. Defendants' Motion for a second stay is nothing more than a strategic tactic to further stall presenting this case to a jury for determination of the substantial damages owed to SRT as a result of Defendants' willful infringement of the Patents-in-Suit.

Defendants did not act with diligence here. A second stay would excessively delay resolution of this competitor case. Had the IPRs been filed within a few months of the complaint (as they often are) the PTAB would have issued final written decisions by now since by statute, IPR final decisions are required to be issued within one year of institution barring unforeseen circumstances.<sup>2</sup> Indeed, there was no change in circumstance between the filing of the initial complaint and the filing of the IPRs nearly a year later that would legitimize the delay. The timing of Defendants' second stay disfavors staying this case for a second time.

---

<sup>2</sup> In general, IPRs take at most six months from petition to institution decision, and at most a year from institution decision to final written decision. *See* 37 CFR § 42.107(b), 35 U.S.C. §§ 314(b), 316(a)(11). Had the petitions been filed December 2021, two months after the October 2021 complaint, the final written decision would have been due this month.

### 3. The Relationship Between the Parties Disfavors a Stay

“Courts are hesitant to grant a stay in a matter where the parties are direct competitors.” *Neste Oil OYJ*, 2013 WL 3353984, at \*3; *ImageVision.Net*, 2013 WL 663535, at \*6. “In such cases, ‘there is a reasonable chance that delay in adjudicating the alleged infringement will have outsized consequences to the party asserting infringement has occurred, including the potential for loss of market share and an erosion of goodwill.’” *Neste Oil OYJ*, 2013 WL 3353984, at \*3 (citation omitted).

SRT and bluebird are direct competitors in the field of gene therapy treatments using lentiviral vectors to treat Beta Thalassemia and Sickle Cell Disease patients. Defendants’ suggestion the SRT and bluebird “are not competitors” is false. (Def. Br. at 9.) In fact, the arbitrator recognized that bluebird and SRT are direct competitors, a fact that bluebird did not dispute during arbitration. (D.I. 87 ¶ 95 (“The transfer by MSK of ‘an exclusive, royalty free commercial license’ to the ’179 and ’061 patents would have had made no sense *if SRT’s one and only commercial competitor, bluebird*, was being given a release to practice the very patent that was being promised in the same agreement to be commercially exclusive.”) (emphasis added); ¶ 96 (“In this respect, based on the unequivocal language of the Settlement Agreement read as a whole, the only reasonable reading of both paragraph 2 and paragraph 5 of the Settlement Agreement is to find that neither SRT nor MSK released *SRT’s only competitor, bluebird*, from any claims to the ’179 and ’061 patents for which an ‘exclusive, royalty free commercial license’ was being granted as one of the two principal items of consideration in the agreement.”) (emphasis added)). Because SRT and bluebird are direct competitors, SRT would be unduly prejudiced by a stay. *See, e.g., F’Real Foods, LLC v. Hamilton Beach Brands, Inc.*, C.A. No. 16-41-GMS, 2017 WL 10619854, at \*1 n.3 (D. Del. March 9, 2016) (denying stay post institution, noting “courts are more hesitant to grant a stay in a matter where the parties are direct competitors.”) (citation

omitted); *Becon Med., Ltd. v. Bartlett*, No. 18-4169, 2019 WL 6910130, at \*3 (E.D. Pa. Dec. 18, 2019) (“Because the parties are direct competitors, plaintiffs would likely be unduly prejudiced by a stay. Additionally, *plaintiffs have presented strong evidence of willful infringement by defendants.*” (emphasis added)).

There is strong evidence of willful infringement in this case. (D.I. 39, SAC, ¶¶ 95-96, 142-162). And it is undisputed that Defendants had prior knowledge of the Patents-in-Suit and was aware that SRT has an exclusive license of the Patents-in-Suit. (D.I. 90, Answer, ¶ 95 (admitting that the Settlement Agreement references the Patents-in-Suit); ¶¶ 143-144, 148 (admitting that TRV visited MSKCC to discuss IP licensing); ¶ 155 (admitting that Nick Leschly (Third Rock) and Mitch Finer (Genetex, now bluebird) wrote an email stating: “Pat Girondi [SRT] – need to shut him down.”)).

Here, as in *Becon Medical*, “[b]ecause the parties are direct competitors and there is strong evidence of willful infringement,” SRT “would be prejudiced by a stay, even though [SRT] did not move for a preliminary injunction.” *Becon Med.*, 2019 WL 6910130, at \*3 (denying motion to stay pending IPR proceeding). “Accordingly, this sub-factor weighs against a stay.” *Id.*

Contrary to Defendants’ argument, the lack of a preliminary injunction request does not insulate this competitive harm, especially since under these facts, where Defendants immediately moved unsuccessfully to try to dismiss this case through an arbitration proceeding that ruled in favor of SRT. *See, e.g., Avanos Med. Sales, LLC v. Medtronic Sofamor Danek USA, Inc.*, C.A. No. 2:19-cv-02754, 2020 WL 7865959, at \*3 (W.D. Tenn. Nov. 24, 2020) (denying stay post-institution, noting “[Plaintiff’s] decision not to seek a preliminary injunction does not mean it would not suffer prejudicial harm from its competitor’s market activity during a lengthy delay in the case.”); *F’Real Foods*, 2017 WL 10619854, at \*1 n.3 (“Whether the non-moving party has

sought a preliminary injunction is not dispositive on the ‘direct competition’ issue”); *Becon Med.*, 2019 WL 6910130, at \*3 (“[W]hether a party sought a preliminary injunction is not dispositive on the issue of whether it would suffer undue prejudice because there are many reasons that a plaintiff might not to move for a preliminary injunction.” (citing *VirtualAgility Inc. v. Salesforce.com, Inc.*, 759 F.3d 1307, 1319 (Fed. Cir. 2014))).) *See also RainDance Techs, Inc. v. 10X Genomics, Inc.*, C.A. No. 15-152-RGA, at 13-14 (D. Del. Apr. 5, 2016) (plaintiff not seeking preliminary injunction should not be a factor in the stay analysis) (Ex. D).

SRT would be substantially prejudiced by a second stay in this case. Time is important here. The applications to the Patents-in-Suit were filed more than twenty years ago and Defendants’ acts supporting willful infringement and copying started more than ten years ago. Witness memories are likely to fade and get worse as the years pass by. *See Intell. Ventures I LLC*, 2015 WL 3773779, at \*2 (“As courts have recognized, plaintiffs ‘will suffer some prejudice from a stay, due to loss of their chosen forum, the possibility of necessary witnesses’ memories fading, and negative impact on their ability to license the patents-in-suit.’”) (citation omitted); *Cf. Robinson v. Walgreen Co.*, C.A. No. 20 CV 50288, 2021 WL 2453069, at \*2 (N.D. Ill. Jun. 16, 2021) (“Given that Defendant has already benefitted from a stay, the Court acknowledges that another stay extending the case even further would be prejudicial to Plaintiffs’ ability to develop its case.”); *see also cf. CMG Worldwide Inc. v. Adidas Am., Inc.*, C.A. No. 1:17-cv-2356-RLM-DML, 2018 WL 7140117, at \*3 (S.D. Ind. Sept. 26, 2018) (“First, the court considers the fact that, in effect, [Defendant] has already had the benefit of a lengthy stay, because this case was filed well over a year ago. Second, a stay that extends even further could prejudice the plaintiff’s ability to develop its case, because the passage of time tends to erode proof of claims and damages.”).

#### 4. The IPRs Should Have Never Been Filed.

The IPR proceedings also run afoul of the Settlement Agreement executed by SRT, bluebird, and MSK (which includes patent owner SKI). Pursuant to Section 5 of the Settlement Agreement, bluebird and MSK (which includes patent owner SKI) exchanged mutual general releases. Under the Settlement Agreement, bluebird agreed to “fully, finally and forever release, relinquish, acquit and discharge [MSK] from and against any and all claims, causes of action, demands, disputes, suits . . . controversies, promises, assessments, rights, damages, costs and/or expenses whether based on a tort, contract or any other theory of recovery, in law, admiralty or equity, whether known or unknown, suspected or unsuspected, asserted or unasserted, foreseen or unforeseen, that [bluebird] may have, ever had or now has against [MSK], for upon or by reason of any cause or thing, from the beginning of the world to the [Parties’] execution of this Confidential Settlement Agreement.” (*See* D.I. 25, Ex. C (Settlement Agreement at § 5).) In the IPRs, bluebird claims that the United States Patent and Trademark Office (“USPTO”) improperly granted and issued the ’179 Patent and ’061 Patent in 2009 and 2011, respectively, based upon allegedly earlier prior art. The IPR petitions are causes of action filed against the patent owner, SKI, that post-date the Settlement Agreement.

More specifically, bluebird’s IPR petitions against SKI claiming the USPTO improperly granted and issued the ’179 Patent and ’061 Patent in 2009 and 2011, respectively, are claims that bluebird released pursuant to the Settlement Agreement. (Ex. E, (May 1, 2023, letter from W. French-Brown to E. Dittmann).) In November 2011, bluebird and SKI executed an option agreement (the “2011 Option Agreement”) that bluebird executed under the false pretense that it was interested in obtaining an exclusive license to SKI’s intellectual property, including the ’179 Patent and ’061 Patent. (*See id.*) Both patents were specifically referenced and identified by their U.S. patent numbers listed under Licensed Patents in Appendix A attached thereto. (*See id.*) Under

the 2011 Option Agreement, bluebird desired a period of time in which to evaluate the '179 Patent and '061 Patent. (*See id.*) To that end, any claims that bluebird may have or had against SKI regarding the validity of the '179 Patent and '061 Patent, or any other patent listed in Appendix A of the 2011 Option Agreement, were released and forever waived by bluebird pursuant to the Settlement Agreement. (*See id.*) SRT believes that Defendants' refusal to withdraw the IPR petitions is further evidence of Defendants' intent to fraudulently induce SRT in November 2020 to execute the Settlement Agreement, and to continue their pattern of unlawful actions in violation of 18 U.S.C. § 1964 *et seq.* and Mass. Gen. Law ch. 93A, § 11 (*see id.*), which are claims that SRT is asserting against Defendants in a related action filed in the District of Massachusetts. (*See D.I. 96.*)

The Arbitrator was so perplexed by Defendants' IPR petitions that he presented the parties with the following question:

Are bluebird's petitions for Inter Partes Review seeking invalidation of the MSK/SRT '179 and '061 Patents-in-Suit ***inconsistent with*** bluebird's position in this Arbitration that the mutual releases in the Settlement Agreement were intended to release patent claims within their scope? Why? Why not?

(*See D.I. 96, Ex. A, ¶ 202.*) During arbitration, it became apparent that the IPR petitions against SKI (patent owner) seeking to invalidate claims of the Patents-in-Suit was contrary to the release provision in the Settlement Agreement. For example, the Arbitrator presented the parties with the following question:

Given that the Settlement Agreement releases are mutual, does the Settlement Agreement release all claims of any kind, known or known, by all three of SRT, bluebird and MSK, against one another, including patent claims at least up to the execution of the settlement agreement? Why? Why not?

(*See D.I. 96, Ex. A, ¶ 203.*) Indeed, the arbitration award mentions that Defendants' October 18, 2022, filings of the two IPR petitions against SKI affirmatively seeking to invalidate the '179 and '061 patents show that Defendants themselves did not feel constrained by their identical releases

to MSK not to bring patent claims against MSK. (*See* D.I. 87 ¶ 97.) The foregoing further illustrates Defendants’ dilatory intent and the undue prejudice to SRT.

Defendants’ Motion improperly claims that “SRT does not have a good faith basis to allege infringement of any claim of the patents-in-suit, including for reasons Defendants have already explained to SRT’s counsel.” (D.I. 98 at 5 n.2.) Again, this is not a relevant argument to show that a second stay is warranted in this case. Nonetheless, SRT’s SAC and initial complaint included over 60 pages of claim charts to exemplify infringement. (*See* D.I. 1, Exs. I-J; D.I. 39, Exs. L-M.) But either way, the district court case is the proceeding that should move forward if Defendants truly believe that infringement is a case dispositive issue. Yet Defendants are doing everything possible to avoid discovery into the FDA-approved BB305 Vector. Indeed, it appears to be Defendants’ goal to drag out and multiply these proceedings as much as possible to the detriment of SRT.

This case has been pending for nearly twenty months. It was previously stayed, at Defendants’ request, to allow Defendants to arbitrate lack of standing and release defenses. The arbitrator ultimately sided with SRT on all issues on February 7, 2023. The parties expended substantial effort in the arbitration, which involved discovery and a hearing before the arbitrator. Thus, a substantial amount of work has already occurred. Defendants are now ignoring the representations they made in obtaining the first stay. In particular, Defendants had argued “an arbitration would be necessary to resolve threshold issues before any alleged infringement claims could proceed.” (D.I. 46 at 3.) Now that it is time for the infringement claims to proceed, Defendants seek yet another stay alleging the validity of some—but not all—asserted claims should be decided first.

For the foregoing reasons, a second stay would unduly prejudice SRT and permit Defendants to gain multiple improper tactical advantages.

**C. The Stage of the Litigation Does Not Warrant a Stay**

Contrary to Defendants' claims (Def. Br. at 1.), this case is not in its early stages. The complaint was filed nearly two years ago in October 2021, and the parties have been litigating some key preliminary and case dispositive issues since January 14, 2022, when Defendants filed their first motion to dismiss or, in the alternative, compel arbitration and stay the proceedings (D.I. 15.) Indeed, the parties spent nearly 6 months in arbitration, which involved discovery, that resolved in SRT's favor Defendants' defense that the release provision in the Settlement Agreement precludes SRT from asserting patent infringement claims against bluebird. (D.I. 87, §§ V.B, VII, IX ("the November 2, 2020 Settlement Agreement does not release SRT's patent claims against Respondents for infringement of the 7,541,179 and 8,058,061 patents.")). The parties are nineteen months into litigating this case. Furthermore, the parties have a Scheduling Order and a trial date is set. (D.I. 101.) At this point, "the parties have already expended significant resources on the litigation and the principle of maximizing the use of judicial and litigant resources is best served by seeing the case through its conclusion." *SenoRx*, 2013 WL 144255, \*5.

**IV. CONCLUSION**

For the foregoing reasons, Defendants' motion for a second stay should be denied.



Dated: June 7, 2023

*Of Counsel:*

Wanda D. French-Brown  
Howard S. Suh  
James H. McConnell  
FOX ROTHSCHILD LLP  
101 Park Avenue, 17th Floor  
New York, NY 10178  
(646) 601-7617  
wfrench-brown@foxrothschild.com  
hsuh@foxrothschild.com  
jmccConnell@foxrothschild.com

Joe G. Chen, Ph.D.  
FOX ROTHSCHILD LLP  
997 Lenox Drive  
Lawrenceville, NJ 08648  
(609) 844-3024  
joechen@foxrothschild.com

Lenore Horton  
HORTON LEGAL STRATEGIES PLLC  
11 Broadway, Suite 615  
New York, NY 10004  
(212) 888-9140  
lenore@hortonlegalstrategies.com

YOUNG CONAWAY STARGATT  
& TAYLOR, LLP

/s/Anne Shea Gaza

Anne Shea Gaza (No. 4093)  
Samantha G. Wilson (No. 5816)  
Rodney Square  
1000 North King Street  
Wilmington, DE 19801  
(302) 571-6600  
agaza@ycst.com  
swilson@ycst.com

*Attorneys for Plaintiff*  
*San Rocco Therapeutics, LLC*